K110280

510(K) Summary: REVLOK™ Fenestrated Screw System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 930-1800

Contact: Kelly J. Baker, Ph.D
Vice President, Regulatory & Clinical Affairs

JUL - 6 2011

Date Prepared: January 28, 2011

Device Name: REVLOK™ Fenestrated Screw System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
Product Codes MNH, MNI, KWQ, NKB.
Regulatory Class II and III, Panel Code 87.

Predicate(s): Globus Medical REVERE® Stabilization System (K061202, K081195 and K091782); and REVOLVE® Stabilization System (K083416) and Theken Spine Coral™ Spinal System (K070962).

Purpose:
The purpose of this submission is clearance of the REVLOK™ Fenestrated Screw System, a modification of the cleared REVERE® and REVOLVE® Stabilization Systems.

Device Description:
The REVLOK™ Fenestrated Screw System consists of monoaxial screws, uniplanar screws, polyaxial screws, dual-outer-diameter screws, reduction screws, rods and locking caps. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy. REVLOK™ implants mate with 5.5mm diameter rods, and 6.35mm implants mate with 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Locking caps are used to connect the screws to the rod.

The most common use of this screw and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws.

The most common use of this screw and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F67, F1537 and F138. All other REVLOK™ implants are manufactured from titanium alloy or stainless steel, as specified in ASTM F136, F1295, F138 and F67. The REVLOK™ Fenestrated Screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

Indications for Use:
The REVLOK™ Fenestrated Screw System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVLOK™ Fenestrated Screw System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVLOK™ Fenestrated Screw System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Performance Data:
Mechanical testing (static and dynamic compression and static torsional) was conducted in accordance with ASTM F1717 and the Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device.

Basis of Substantial Equivalence:
The REVLOK™ Fenestrated Screw System is similar to the predicates REVERE® and REVOLVE® Stabilization System implants with respect to

technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Inc.
% Kelly J. Baker, Ph.D.
Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 13403

JUL - 6 2011

Re: K110280
Trade/Device Name: REVLOK™ Fenestrated Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ
Dated: June 14, 2011
Received: June 15, 2011

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

"The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (301) 796-6926. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health
Food and Drug Administration

Enclosure

Indications for Use Statement

510(k) Number: K110280

Device Name: REVLOK™ Fenestrated Screw System

INDICATIONS:

The REVLOK™ Fenestrated Screw System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVLOK™ Fenestrated Screw System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVLOK™ Fenestrated Screw System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Prescription Use ___X___ OR Over-The-Counter Use_____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110280